4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0554]

Actavis Elizabeth LLC, et al.; Withdrawal of Approval of 85 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 85 abbreviated new drug applications (ANDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993-0002, 240-402-6980, Martha.Nguyen@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process described in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
ANDA 040113	Chlorzoxazone Tablets, 500 milligrams (mg)	Actavis Elizabeth LLC (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Building A, Parsippany, NJ 07054
ANDA 040152	Carisoprodol Tablets, 350 mg	Watson Laboratories, Inc. (an indirect, wholly

Application No.	Drug	Applicant
		owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Building A, Parsippany, NJ 07054
ANDA 040184	Trihexyphenidyl Hydrochloride (HCl) Tablets, 2 mg and 5 mg	Do.
ANDA 040212	Estradiol Tablets, 0.5 mg, 1 mg, 1.5 mg, and 2 mg	Do.
ANDA 040276	Phentermine HCl Tablets, 37.5 mg	Actavis Elizabeth LLC
ANDA 040296	Estropipate Tablets, 0.75 mg, 1.5 mg, and 3 mg	Barr Laboratories, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Building A, Parsippany, NJ 07054
ANDA 060704	Tetracycline HCl Capsules, 250 mg and 500 mg	Ivax Pharmaceuticals, Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Building A, Parsippany, NJ 07054
ANDA 062343	Tetracycline HCl Capsules, 250 mg and 500 mg	Watson Laboratories, Inc.
ANDA 062581	Doxycycline Hyclate Tablets, Equivalent to (EQ) 100 mg base	Teva Pharmaceuticals USA, Inc., 400 Interpace Pkwy., Building A, Parsippany, NJ 07054
ANDA 070152	Diazepam Tablets, 2 mg	Barr Laboratories, Inc.
ANDA 070153	Diazepam Tablets, 5 mg	Teva Pharmaceuticals USA, Inc
ANDA 070154	Diazepam Tablets, 10 mg	Barr Laboratories, Inc.
ANDA 070511	Metoclopramide HCl Tablets, EQ 10 mg base	Watson Laboratories, Inc.
ANDA 070548	Propranolol HCl Tablets, 10 mg	Do.
ANDA 070706	Diazepam Tablets, 5 mg	Actavis Elizabeth LLC
ANDA 070707	Diazepam Tablets, 10 mg	Do.
ANDA 070781	Diazepam Tablets, 2 mg	Do.
ANDA 070856	Verapamil HCl Tablets, 120 mg	Watson Laboratories, Inc.
ANDA 070944	Oxazepam Capsules, 15 mg	Ivax Pharmaceuticals, Inc.
ANDA 070964	Clonidine HCl Tablets, 0.2 mg	Watson Laboratories, Inc.
ANDA 070965	Clonidine HCI Tablets, 0.1 mg	Do.
ANDA 070985	Ibuprofen Tablets, 200 mg	Merro Pharmaceutical Co., Ltd., SciRegs International, Inc., Authorized U.S. Agent, 6333 Summercrest Dr., Columbia, MD 21045
ANDA 071019	Verapamil HCl Tablets, 80 mg	Actavis Elizabeth LLC
ANDA 071050	Morphine Sulfate Injection, 0.5 mg/milliliters (mL)	Fresenius Kabi USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047
ANDA 071086	Lorazepam Tablets, 0.5 mg	Watson Laboratories, Inc.
ANDA 071087	Lorazepam Tablets, 1 mg	Do.
ANDA 071088	Lorazepam Tablets, 2 mg	Do.
ANDA 071366	Verapamil HCl Tablets, 80 mg	Do.
ANDA 071367	Verapamil HCl Tablets, 120 mg	Do.
ANDA 071476	Betamethasone Dipropionate Cream, EQ 0.05% base	Teva Pharmaceuticals USA, Inc.
ANDA 071477	Betamethasone Dipropionate Ointment, EQ 0.05% base	Do.

Application No.	Drug	Applicant
ANDA 071479	Carbamazepine Tablets, 200 mg	PLIVA Inc. (an indirect, wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Building A, Parsippany, NJ 07054
ANDA 071696	Carbamazepine Tablets, 200 mg	Actavis Elizabeth LLC
ANDA 071969	Triamterene and Hydrochlorothiazide Tablets, 50 mg and 75 mg	Watson Laboratories, Inc.
ANDA 072124	Verapamil HCl Tablets, 80 mg	PLIVA Inc.
ANDA 072125	Verapamil HCl Tablets, 120 mg	Do.
ANDA 072333	Prazosin HCl Capsules, EQ 2 mg base	Watson Laboratories, Inc.
ANDA 072352	Prazosin HCl Capsules, EQ 1 mg base	Do.
ANDA 072418	Amoxapine Tablets, 25 mg	Do.
ANDA 072419	Amoxapine Tablets, 50 mg	Do.
ANDA 072420	Amoxapine Tablets, 100 mg	Do.
ANDA 072421	Amoxapine Tablets, 150 mg	Do.
ANDA 072609	Prazosin HCl Capsules, EQ 5 mg base	Do.
ANDA 072751	Verapamil HCl Tablets, 40 mg	PLIVA Inc.
ANDA 072923	Verapamil HCl Tablets, 40 mg	Watson Laboratories, Inc.
ANDA 072953	Oxazepam Capsules, 15 mg	Do.
ANDA 072954	Oxazepam Capsules, 30 mg	Do.
ANDA 073093	Baclofen Tablets, 20 mg	Do.
ANDA 073122	Loperamide HCl Capsules, 2 mg	Teva Pharmaceuticals USA, Inc.
ANDA 073334	Amiloride HCl and Hydrochlorothiazide Tablets, EQ 5 mg anhydrous; 50 mg	Watson Laboratories, Inc.
ANDA 073352	Atenolol Tablets, 50 mg	Do.
ANDA 073353	Atenolol Tablets, 100 mg	Do.
ANDA 073637	Piroxicam Capsules, 10 mg	Teva Pharmaceuticals USA, Inc.
ANDA 073638	Piroxicam Capsules, 20 mg	Do.
ANDA 074026	Triamterene and Hydrochlorothiazide Tablets, 25 mg and 37.5 mg	PLIVA Inc.
ANDA 074359	Butalbital, Aspirin, Caffeine, and Codeine Phosphate Capsules, 325 mg, 50 mg, 40 mg, and 30 mg	Watson Laboratories, Inc.
ANDA 074405	Flurbiprofen Tablets, 50 mg and 100 mg	Teva Pharmaceuticals USA, Inc.
ANDA 074421	Cyclobenzaprine HCl Tablets, 10 mg	PLIVA Inc.
ANDA 074436	Cyclobenzaprine HCl Tablets, 10 mg	Watson Laboratories, Inc.
ANDA 074442	Gemfibrozil Tablets, 600 mg	Do.
ANDA 074479	Alprazolam Tablets, 0.25 mg, 0.5 mg, and 1 mg	Do.
ANDA 074647	Flurbiprofen Tablets, 50 mg and 100 mg	PLIVA Inc.
ANDA 074762	Guanfacine HCl Tablets, EQ 1 mg base and EQ 2 mg base	Watson Laboratories, Inc.
ANDA 074836	Acyclovir Tablets, 400 mg and 800 mg	IVAX Pharmaceuticals, Inc.
ANDA 074892	Etodolac Tablets, 400 mg and 500 mg	Watson Laboratories, Inc.
ANDA 074955	Ketorolac Tromethamine Tablets, 10 mg	Do.
ANDA 074964	Clonazepam Tablets, 0.5 mg, 1 mg, and 2 mg	Do.
ANDA 075067	Cromolyn Sodium Inhalation Solution,	Actavis Mid Atlantic LLC (an indirect, wholly owned subsidiary of Teva

Application No.	Drug	Applicant
	10 mg/ mL	Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Building A, Parsippany, NJ 07054
ANDA 075069	Etodolac Tablets, 400 mg	Watson Laboratories, Inc.
ANDA 075262	Albuterol Sulfate Syrup, EQ 2 mg base/5 mL	Actavis Mid Atlantic LLC
ANDA 075284	Ketorolac Tromethamine Tablets, 10 mg	PLIVA Inc.
ANDA 081165	Hydroxyzine Pamoate Capsules, EQ 25 mg HCl	Watson Laboratories, Inc.
ANDA 084503	Hydralazine HCl Tablets, 50 mg	Do.
ANDA 085054	Hydrochlorothiazide Tablets, 25 mg	Actavis Mid Atlantic LLC
ANDA 085084	Prednisone Tablets, 5 mg	Watson Laboratories, Inc.
ANDA 085085	Prednisolone Tablets, 5 mg	Do.
ANDA 085208	Hydrochlorothiazide Tablets, 50 mg	Actavis Elizabeth LLC
ANDA 086710	Aspirin, Butalbital, Caffeine Tablets, 325 mg, 50 mg, and 40 mg	Do.
ANDA 086813	Prednisone Tablets, 20 mg	Watson Laboratories, Inc.
ANDA 087773	Prednisone Tablets, 10 mg	Do.
ANDA 088348	Hydroxyzine HCl Tablets, 10 mg	Do.
ANDA 088349	Hydroxyzine HCl Tablets, 25 mg	Do.
ANDA 088350	Hydroxyzine HCl Tablets, 50 mg	Do.
ANDA 088497	Methylprednisolone Tablets, 4 mg	Duramed Pharmaceuticals Inc. (an indirect wholly owned subsidiary of Teva Pharmaceuticals USA, Inc.), 400 Interpace Pkwy., Building A, Parsippany, NJ 07054
ANDA 089536	Acetaminophen, Butalbital, and Caffeine Tablets, 325 mg, 50 mg, and 40 mg	Watson Laboratories, Inc.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: July 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.
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